UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,133	06/11/2001	Janice Au-Young	PF-0589 USN	5220

22428 7590 06/29/2004

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,133	AU-YOUNG ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) *30,32-34 and 37-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-29,31,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Amendments 4/9/04, 3/5/04 have been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action 12/3/03.

Rejoinder

3. Applicants have requested rejoinder of claims 32-34, 37-40. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to**

do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01

3.

Claim Rejections under 35 USC § 112, Second Paragraph

4. Claims 21 and 31 and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 31 remain indefinite because it is not clear when a nucleic acid molecule or polypeptide is considered naturally occurring as compared to when it is not naturally occurring so as to allow the metes and bounds of the claim to be determined. Applicants argues "naturally occurring" merely refers to the source of the amino acid or polynucleotide sequence, i.e., the sequence must be found in nature. Further Applicants state, "However, the polypeptide or polynucleotide recited by the claim can be made by any means, such as isolation from nature or manufacture by chemical or recombinant methods. It is the amino acid or polnucleotide sequence which must be found in nature." Applicants' arguments have been fully considered but not found persuasive. One can make a nucleic acid molecule comprising a polypeptide having at least 90% sequence identity to SEQ ID NO: 25 or SEQ ID NO: 7, respectively, by randomly mutating, say one base, of the nucleic acid molecule disclosed in SEQ ID NO: 2. The question is would this mutated molecule be considered "naturally occurring" or

not "naturally occurring". At this moment in time this determination is impossible to make. Not until every possible sequence and mutation in every living cell has been determined, to serve as a comparison, can one even begin to formulate an opinion as to wheatear the molecule is "naturally occurring". If the mutation created in the laboratory, which was initially classified as not naturally occurring, is found in a living cell, does the nucleic acid molecule then become naturally occurring? Therefore by merely looking at a nucleic acid molecule it can be determined if a sequence is a naturally molecule as compared to not naturally occurring. What specific critical feature of the invention allows the nucleic acid molecule to be classified as naturally occurring as compared to not naturally occurring? Would any recombinant nucleic acid introduced into a host cell and that replicates in said host cell could be considered naturally occurring?

Claims 35-36 are rejected for depending upon an indefinite base (or intermediate) claim and fail to resolve the issues raised above.

Claim Rejections under 35 USC § 101

5. Claims 22-29, 31 and 35-36 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for reason set forth below and the Office Action dated 12/3/03.

Applicants argues the claimed invention has numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of

disease, none of which requires knowledge of how the polypeptide coded for by the polynucleotide actually functions. Applicants submit two Declarations under 37 C.F.R. 1.132, The Rockett Declaration and the Iyer Declaration.

Applicants and the Declarations of the Rockett Declaration and the Iyer Declaration argue that it was well-established in the art that:

a) polynucleotides can be used as hybridization probes;

b) expression analysis is useful, in drug discovery and lead optimization efforts;

c) nucleic acid microarrays increase the parallelism of expression measurements;

d) it is not necessary that the biological function of a gene be known for measurement of its expression to be useful in drug discovery and lead optimization analyses, toxicology, or molecular phenotyping experiments.

Applicants' arguments, the Rockett Declaration and the Iyer Declaration have been fully considered but are not found persuasive. Applicants have not disclosed the cellular function or activity of claimed polynucleotide/polyeptide but argued that it can be used a research tool. Applicants claim MECHP-7 is useful in screening but the specification does not disclose what claimed MECHP-7 specifically regulates and what specific disease, claimed MECHP-7, is a target for. What would be the use of using the claimed MECHP-7on a panel for drug screening? The MECHP-7 has no known ligand or known function. How would one use the compounds that interacted with said orphan MECHP-7? It is unpredictable what ligands will bind to orphan MECHP-

7 and which compounds are transported. Further the functional effects of ligand binding and compound transport may remain uncertain even after extensive experimentation. What is the utility for a ligand ,in many cases with no known function, that binds to a MECHP-7 of no known function? The ordinary artisan can only speculate on the utility for the ligand and MECHP-7. A utility to orphan MECHP-7 cannot be assigned without knowledge of what disease is associated with claimed MECHP-7 dysfunction or what drugs/ligands affect a specific claimed MECHP-7 function.

The claims encompasses nucleic acid molecules encoding variants of the protein disclosed in SEQ ID NO:7, said variants may be completely unrelated, structurally and functionally to the protein encoded by the polynucleotide of SEQ ID NO:25. The superfamily of ion channels are highly divergent in their effects, solutes transported and ligand specificity as disclosed in the specification (see previous Office action). There is no disclosure of the specific compounds transported or specific ligands that activate or bind claimed MECHP-7. The exact role of MECHP-7 in any disease state or non-disease state has not been disclosed. There is no disclosure of the specific disease state involved in MECHP-7 dysfunction. It is not known if MECHP-7 expression is increased or decreased in said dysfunction. Therefore, it is not known which disease to treat by altering the functionality or expression of MECHP-7. Further, it is not known whether increased expression MECHP-7 is beneficial or detrimental to the host. Also, it is not known whether increased expression MECHP-7 is detrimental to the host. There is no disclosure of the specific activity of claimed MECHP-7 or

how to assay for said activity. In light of the specification the skilled artisan cannot come to any conclusions as to the function of claimed nucleic acid encoding the MECHP-7or variants thereof. The superfamily of ion transporters is highly divergent in their effects and compound specificity. The problems of using homology detection methods to assigning function to related members of a family in the previous Office Action (see Bork , Karp)

The claimed MECHP-7 may have utility in the future, when it has been further characterized (e.g. its dysfunction or function correlated with a disease state) and its ligand or compound transported characterized and functionality determined. The inclusion in the family of ion channels does not constitute either a specific and substantial asserted utility or a well-established utility for that particular MECHP-7 or protein. This is analogous to all proteins/nucleic acid of ion channels can be used as markers on a gel.

All members of the ion channels family have a use in selectively screening of candidate drugs that target ion channels. However, for a utility to be "well-established" it must be specific, substantial. In this case, as all MECHP-7 are in some combination useful in selectively screening of candidate drugs that target ion transporters and in toxicology testing. However, the particulars of screening of candidate drugs, that target claimed MECHP-7, and in toxicology testing are not disclosed in the instant specification. Neither the candidate drugs or toxic substances nor the susceptible organ systems are identified. Therefore, this is a utility, which would apply to virtually every member of a general class of materials, such as any collection of proteins or DNA, but is only potential with

respect to SEQ ID NO:7 and 25. Because of this, such a utility is not specific and does not constitute a "well-established" utility. Further, because any potential diagnostic utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. Moreover, use of the claimed protein for screening compounds that are a target for claimed MECHP-7is only useful in the sense that the information that is gained from the assay/array and is dependent on the effect it has on the protein/nucleic acid, and says nothing with regard to each individual member of the MECHP-7 family. Again, this is a utility, which would apply to virtually ever member of a general class of materials, such as any collection of proteins or DNA. Even if the expression of Applicants' individual MECHP-7 is affected by a test compound in an assay/array for drug screening, the specification does not disclose any specific and substantial interpretation for the result, and none is known in the art. Given this consideration, the individually claimed method of using claimed MECHP-7 has no "well-established" use. The artisan is required to perform further experimentation on the claimed MECHP-7itself in order to determine to what "use" any information regarding this protein could be put.

With regard to diagnosis of disease, in order for a polynucleotide or protein to be useful, as asserted, for diagnosis of a disease, there must be a well established or disclosed correlation or relationship between the claimed MECHP-7and a disease or disorder. The presence of claimed MECHP-7in tissue is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression

of the claimed MECHP-7 and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed MECHP-7 to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed MECHP-7is either present only in, e.g. cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. over expression). Evidence of a differential expression might serve as a basis for use of claimed MECHP-7as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed MECHP-7and any disease or disorder and the lack of any correlation between the claimed VR-L with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

The assertion that the claimed invention has utility in drug screening, drug development and disease diagnosis, do not meet the standards for a specific, substantial or well-established utility for reasons set forth above. None of the utilities identified have been demonstrated to be specific to the polypeptide encoded by the nucleic acid of SEQ ID NO:25 . One of ordinary skill in the art

must understand how to achieve an immediate and practical benefit from the claimed species based on the knowledge of the class. However, no practical benefit has been shown for the use of the polypeptide SEQ ID NO:7 or the polynucleotide of SEQ ID NO:25. Applicant has failed with respect to claimed MECHP-7, has not described the family of MECHP-7in enough detail to show, by a preponderance of the evidence, that the polypeptide of SEQ ID NO:7 or the polynucleotide of SEQ ID NO:25 or variants thereof has any substantial use. For all the above reasons, the disclosure is insufficient to teach one of skill in the art how to use the invention. The use of the claimed invention for toxicology testing, drug discovery, and disease diagnosis are not substantial utilities.

Claim Rejections under 35 USC § 112, 1st paragraph

6. Claims 20-29, 31, 35-36 remain rejected under 35 U.S.C. 112, first paragraph for reason given below and those in the Office Action dated 12/3/03.

Applicants argue that the disclosure amply enables the claimed invention. Given the sequence of SEQ ID N0:25, one of ordinary skill in the art could readily identify a polynucleotide comprising a naturally occurring polynucleotide sequence at least 90% identical to a polynucleotide sequence of SEQ m NO:25, using well known methods of sequence analysis without any undue experimentation. The skilled artisan would also know how to use the claimed polynucleotides, for example in expression profiling, disease diagnosis, or detection of related sequences as discussed above. Applicants also argue that

the claims of the instant application are drawn to naturally occurring variants. Thus it is not necessary to screen every conceivable variant, which might be made using recombinant methods since those variant sequences, which are found in nature, are claimed.

Applicant's arguments have been fully considered but not found persuasive. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, in the Office Action dated 12/3/03, one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed MECHP-7, polynucleotide (SEQ ID NO:25) encoding the polypeptide of SEQ ID NO:7, variants thereof. Further experimentation is necessary to attribute a utility to the claimed nucleic acid encoding MECHP-7 polypeptides and variants thereof and methods of use.

The claims are not limited to naturally occurring compounds as claimed by Applicants. The claims are drawn to an orphan MECHP-7 and billions of variants thereof. The claimed nucleic acid encodes an orphan MECHP-7 whose activity, compound transported, activating ligands and functionality have not been disclosed. Neither the claims nor the specification disclose what specific biological activity is associated with the claimed MECHP-7. There is no disclosure of the specific compounds that are transported, proteins activated in the signal transudation pathway or what ligand is capable of binding to the polypeptide encoded by the claimed polynucleotide, so as to disclose a specific

function for the claimed polynucleotide. Therefore nucleic acid encoding unrelated and inactive proteins are encompassed by the claims. The specification does not disclose how to produce active variants or how to use inactive ones. Billions of the polypeptides of MECHP-7 encompassed by the claims may be inactive or unrelated to the nucleic acid encoding the polypeptide of SEQ ID NO:7. There is no disclosure of how to assay variants of MECHP-7 identified by any procedure, since the ligand, compound transported and function of the claimed invention is unknown.

Therefore, since the claimed compounds have no utility and are not enabled for reasons set forth above and in the previous Office Action (dated 12/3/03), vector comprising the claimed nucleic acid, cells comprising said vector, composition comprising claimed nucleic acid and method of producing polypeptide encoded by claimed nucleic also rejected under 35 USC § 112, 1st paragraph

Claim Rejection 35 USC § 112, 1st paragraph (Written Description)

7. Claims 21, 23, 26-28, 31 and 35 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reason given below and those in the Office Action dated 12/3/03.

Applicants argue SEQ ID NO:7 and SEQ ID NO:25 are specifically disclosed in the application . Variants of SEQ ID NO:7 and SEQ ID NO:25 are described. Chemical and structural features of SEQ ID NO:7 are described. One of ordinary skill in the art would recognize a polynucleotide comprising a naturally occurring polyucleotide sequence at least 90% identical to the polynucleotide sequence of SEQ ID NO:25. Accordingly, the Specification provides an adequate written description of the recited polypeptide and polynucleotide sequences. The present claim specifically claim the genus through the recitation
of chemical structure. The present claims do not define a genus, which is "highly variant".

Applicants' arguments have been fully considered but are not found persuasive. The number of possible variants encompassed by Applicants' claims potentially out numbers all the molecules in the universe. All the claimed variants have no disclosed function. The claims encompasses nucleic acid molecules encoding variants of the protein disclosed in SEQ ID NO:7, said variants may be completely unrelated, structurally and functionally to the protein encoded by SEQ ID NO:25 . The common function of the nucleic acid (SEQ ID NO:25) encoding the polypeptide (SEQ ID NO:7), which is based upon a common property or critical technical feature of the genus claimed is not disclosed. The claims, as written, encompass nucleic acid encoding polypeptides, which vary substantially in length and also in amino acid composition. The instant disclosure of a polynucleotide of SEQ ID NO:25 encoding the polypeptide of SEQ ID NO:25 does not adequately describe the scope of the use of the claimed genus, which

encompasses a substantial variety of subgenera including polynucleotides, proteins, variants of said polynucleotides and proteins, allelic variants, chimeric constructs, fusion constructs, variants and polynucleotides, which may encode polypeptides completely, unrelated functionally/structurally to the polypeptide of SEQ ID NO:7. A description of a genus of polypeptides/polynucleotides may be achieved by means of a recitation of a representative number of polypeptides/polynucleotides, defined by amino acid/nucleic acid sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the claimed genus of polypeptides/polynucleotides. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. For example, what regions and fragments of the claimed invention contain a definitive structural feature required for protein function? The specification proposes to discover other members of the genus by using screening assays and techniques involving probes, primers, and hybridization. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to

enable one of skill to isolate and identify the polynucleotides and proteins encompassed. No identifying characteristic or property of the instant polypeptides/polynucleotide is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific polypeptide and nucleotide sequences and the inability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe, enable and use the genus as broadly claimed. The skilled artisan cannot envision the detailed chemical structure of the encompassed proteins and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. It is acknowledged that the skill of the artisan in the molecular biology art is high. However, in the current instance, **there is no clear evidence of activity possessed by the claimed genus of nucleic acid molecules encoding variant MECHP-7 polypeptides, the critical special technical feature of the polypeptides or how the critical special technical feature encompassed by the genus claimed relates to function.** Because of the lack of guidance in the prior art and current application, one skilled in the art could not predict if the variants MECHP-7 have the same activity as the protein

disclosed in SEQ ID NO:7, since no activity is disclosed, or if they contain the domain(s) of SEQ ID NO:7, containing the critical special technical feature of the claimed MECHP-7 , since no critical special technical feature is disclosed.

Pertaining to variants to the nucleic acid/protein 90% identical to SEQ ID NO:25/SEQ ID NO:7 the specification does not disclose the critical feature, which must be contained in said nucleic acids/proteins, which is required for activity. The skilled artisan cannot envision the detailed chemical structure of the encompassed compounds and, therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The

nucleic acid or polypeptide is itself is required. See *Fibers v. Revel*, 25 USPQ d. 1601 at 1606 (CAFC 1993) and *Amen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". Therefore the specification fails to disclose the activity of the claimed genus of polypeptides/polynucleotides, the critical special technical feature of the polypeptides/polynucleotides or how the critical special technical feature encompassed by the fragments and variants of claimed MECHP-7 relates to function. The claims encompass nucleic acids encoding proteins, which are structurally and functionally unrelated to the protein/nucleic acid disclosed in SEQ ID NO:7 and 25, respectively. Therefore instant specification fails to provide sufficient descriptive information, such as definitive structural/ functional features of the claimed genus of nucleic acids/polypeptides . There is no description of the conserved regions, which are

critical to the structure, and function of the genus claimed. There is no disclosure of the specific activity of claimed MECHP-7 and how it is specifically assayed. The neither specification nor claims disclose the specific activity of the MECHP-7 of instant invention nor a description of the conserved regions which are critical to the structure and function of the genus claimed.

There is no disclosure of the compound transported by the claimed genus nucleic acids encoding a MECHP-7 or the nature of the signal or specific signal transduction pathway. The claimed nucleic acid encodes an orphan MECHP-7 whose activity, associated function and activating ligands have not been disclosed. The neither specification nor prior art provide a specific assay for the genus claimed. Nucleic acids/proteins comprising variants 90% identical to claimed MECHP-7 may be completely unrelated to the protein encoded by the nucleic acid of SEQ ID NO:25 The complexity of assigning a function and membership into a the genus of proteins is highlighted by Bork and Karp (discussed above), who disclose assigning function by homology is unpredictable by using the complete sequence of an protein, let alone using variants which may not have any domains related to a particular function. Neither the claims nor the specification disclose what specific biological activity is associated with the claimed MECHP-7 or the special technical feature encompassed by specific domains associated with a specific activity of the claimed genus. The superfamily of ion transporters are specialized proteins designed for chemical recognition of ligands, transport of specific compounds, and subsequent transduction of information encoded in those ligands/compounds

to the machinery of the cell. Ion transporters interact with many diverse compounds having diverse effects. The important features, which would help to define the MECHP-7 activity and define the genus claimed, have not been disclosed in the specification nor prior art. Further the activity transduced is not disclosed or how it relates structure to function.

The claims encompass nucleic acids encoding proteins, which are structurally and functionally unrelated to the protein of SEQ ID NO:7. Therefore instant specification fails to provide sufficient descriptive information, such as definitive structural/ functional features of the claimed genus of polypeptides/polynucleotides. There is no description of the conserved regions, which are critical to the structure, and function of the genus claimed. The neither specification nor claims disclose the specific activity of the "orphan MECHP-7 " of instant invention, how it is assayed, nor a description of the conserved regions which are critical to the structure and function of the genus claimed. Further vector comprising the claimed nucleic acid, cell comprising said vector, composition comprising claimed nucleic acid and method of using claimed MECHP-7 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. No claim is allowed

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Gary S. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal s. Basi
Art Unit 1646.
June 28, 2004.